

REMARKS

Claims 1-4, 16, 17, 18 and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (4,932,965) in view of SU 513696.

Applicants respectfully traverse the rejection of the claims. The present invention relates to the use of a visual indicator associated with the strands of a suture system in which two strands are attached to the same needle and can be visually distinguished from each other.

The rejection of the claims appear to be based at least in part on Ex parte Pfeiffer, 135 U.S.P.Q 31 (1962), where it was indicated that in order to be entitled to weight in method claims, the recited structure limitations "must affect the method in a manipulative sense...".

Applicant notes that claim 5 expressly recites that using the visual indicator to identify each strand and then secure it to another strand. Method claims 1 and 21 have been amended to further clarify how the structure affects the method "in a manipulative sense." More specifically, the indicator of the strands are used in attaching the prosthetic device to the tissue, which is not the case in the facts of Ex parte Pfeiffer.

Phillips does not teach or suggest the recited solution to this problem. Phillips utilizes different colors for different sutures 26, i.e., for different pairs of needles. By only using two needles connected by a single suture strand (see Fig. 2 where each suture 26 has opposite ends 28 and 30, which are the same color), Phillips does not have the problem of having the same color strands passing through the same hole. Phillips does not teach or suggest a structure in which a particular needle is attached to two suture strand portions that can be visually distinguished from each other. Phillips does not address the problem the present invention is meant to solve. When a double stranded suture is employed, there are two strands that follow a needle through the same hole in the tissue. Because the two strands are positioned in the same hole they can not readily be distinguished from each other without use of the present invention. For Philips, the different sutures are spatially separated and thus does not address the same problem. If Philips attempted to pass two needles through the same hole, there is a risk of what has been termed a "William Tell" (see page 8, lines 3-14 of the application) where the second needle actually goes through the first suture strand that was previously inserted, thereby risking a break of the suture and/or bleeding through the

hole. The alleged combination of Philips with SU 513696 is not obvious because there is no teaching that different color suture threads be attached to the same needle. The contention in the Office Action that it would be obvious "to apply the known improvement technique (color coding) in the same way..." Applicants respectfully note that the use of the color coding as taught by Phillips with the device of SU '696 is not "in the same way" as set forth in the claimed invention. Phillips discloses that "Upon all sutures 26 being place as seen in Fig. 6 the sewing ring 16 is seated against the annulus 40 body tissue and the opposite ends 28 and 30, having a common color, are tied into a knot 42" (Phillips at Col. 2, lines 40-44). Phillips teaches that the strand connecting the needles be the same color and that different pairs of needles have different colors. This is not "the same way." Additionally, the SU 513696 reference does not disclose or suggest that the device is suitable for suturing a prosthetic implant. Consequently, it would not be obvious to employ a larger number of needles for securing a prosthetic implant that are interconnected by different indicators or colors. For example, nowhere is it suggested that alternating colors (claim 20) or three different colors be used in the cited references. The remaining references

fail to suggest that a plurality of double stranded sutures be used for suturing a prosthetic device.

Claims 5-8, 10, 11 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Soviet Patent No. 513696 ('696) and further in view of Phillips. Claims 12 and 19 has been rejected under 35 U.S.C. 103(a) as being unpatentable over the SU '696 patent and Phillips and further in view of Alpern. Claims 5-8, 10, 11 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over SU '696 and further in view of Phillips. Claim 9 has been rejected under 35 U.S.C. 103(a) as being unpatentable over SU '696 and Phillips '965 and further in view of Ablaza. Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over SU '696 and Phillips and further in view of Ovil.

Applicants respectfully traverse these rejections of the claims. The SU 513696 reference uses thread (1) with 3 needles with no way to distinguish between thread segments passing through the same hole (e.g. 6 and 7). Additionally, the SU 513696 reference relates to the joining of two tissue layers (3 + 4) and does not disclose or suggest the use of the system for suturing a prosthetic device. However, Phillips does not suggest the solution provided by the present invention. Phillips teaches that

different colored threads be attached to different pairs of needles. Phillips does not teach that two different threads, that are distinguishable from each other, can be attached to the same needle.

With respect to Ovil, there is no disclosure or suggestion of how to use a suture placement device with the claimed invention in which at least three needles are connected by suture strands. Ovil teaches that "all suture 10 to be used in suturing the valve in place are applied by knotting one of their ends and passing the suture through a slot 14...". This Ovil system cannot be used with the present invention as it requires knotting of the ends before placement.

The rejection of claims is believed to be obviated in view of the above amendments and remarks. New claims 25-28 have been added for consideration.

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The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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